

REMARKS/ARGUMENTS

After entry of this paper, claims 2-7, 9, and 12-14 are pending. Claims 8, 10, 11, and 15-43 are canceled, without prejudice, as being drawn to non-elected subject matter. Claim 14 is amended to remove non-elected subject matter. Applicants reserve the right to prosecute the non-elected subject matter in a divisional application.

Claim 1 is canceled for clarification purposes. Claim 4 is drafted in independent form. No new matter is added by these amendments.

35 USC § 112, First Paragraph Rejection

Claims 1-7, 9, and 12-14 are rejected under this section for not being enabled for SERMS aside from those provided on page 21 of the specification.

The Examiner also asserted that the claims encompass any and all kinds of SERMs; that Applicant fails to set forth the criteria that define a "SERM"; and there is no working example incorporating the SERMS listed.

Applicants respectfully request reconsideration and withdrawal of this rejection for the following reason.

The cancellation of claim 1 moots the outstanding rejection as applied to this claim.

While the court in *Ex parte Forman* recited eight factors that may be considered when determining if a disclosure does not sufficiently enable claims and therefore would require undue experimentation in order to practice¹, it is not imperative that all of these eight factors must be fulfilled. In fact, the court noted that "[i]t should be emphasized that the absence of a working example was not in itself stated to cause the specification to be insufficiently enabling. It was mentioned merely as one of the factors..."² This is reiterated in MPEP § 2164.2, in which it is stated that "[c]ompliance with the enablement

¹ These factors were set forth in *Ex parte Forman*, 230 USPQ 546 (BDApp's 1986), 547

² *Ex parte Forman*, 230 USPQ 546 (BDApp's 1986), 549

requirement...**does not** turn on whether an example is disclosed"³ (emphasis added). Further, "[t]he specification need not contain an example if the invention is otherwise disclosed in such manner that one of skilled in the art will be able to practice it without an undue amount of experimentation."⁴

Applicants therefore maintain that a working example is not required to fulfill the requirements of § 112, first paragraph. The Examiner indicated that "...one of skill in the art would be required to assess each embodiment individually for physiological activity in order to practice the full scope of the invention".⁵ Applicants, however, assert that this would not be undue experimentation. In order to practice claimed invention for contraception, the specification more than supports the claimed invention in order for one of skill in the art practice the same without undue experimentation. Specifically, the specification provides additional components (page 20, lines 1-19; page 34, line 9 through page 35, line 15; page 40, line 6 through page 41, line 22) that may be utilized in a composition containing the compound of formula I and the selective estrogen receptor modulator (SERM); routes of administration of the components/compositions (page 33, lines 6-16 and page 35, line 18 through page 37, line 8); dosages for the compounds of formula I and the SERM (page 34, lines 4-9); and administration regimens (page 37, line 30 through page 40, line 2). By using this information, one of skill in the art would readily be able to prepare the claimed compositions, perform the claimed methods, and test the claimed compounds of formula I in combination with the selective estrogen receptor modulators (SERMs) provided in the specification, as well as other SERMS, to determine the effectiveness of the same in contraception.

Reconsideration of this rejection is requested.

³ MPEP page 2100-189, column 1, 2nd full paragraph

⁴ MPEP page 2100-189, column 1, 4th full paragraph

⁵ Page 4, lines 5-7 of the Office Action dated October 12, 2006

35 USC § 103(a) Rejection

Claims 1-7, 9, and 12-14 are rejected under this section over US Patent No. 6,355,648 ('648) and US Patent No. 6,331,562 ('562).

Applicants respectfully request reconsideration and withdrawal of this rejection for the following reason.

The cancellation of claim 1 moots the outstanding rejection as applied to this claim.

The motivation to select the claimed compounds for use in combination with a selective estrogen receptor modulator must be taught by the prior art.⁶ This motivation is required in order for the Examiner to make a proper obviousness rejection. Further, in making an obviousness rejection, the Examiner is required to consider the size of the genus claimed (MPEP 2144.08).

As the Examiner is aware, there are a large number of antiprogestin compounds known in the art which may be useful for contraception. Therefore, in order to make a proper rejection, the Examiner is required to consider the size of the genus of antiprogestins, of which one of skill in the art would readily recognize as being considerably large, and point to the motivation in the art to select the claimed compounds for use in combination with one or more selective estrogen receptor modulators (SERM).

The Examiner has argued that "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to employ both the compounds of '648 and '562 in a method of inducing contraception".⁷ However, there is no motivation in either '648 or '562, or any combination of any document in the art, to utilize the compounds of '648 with SERMs for any use, including contraception. The Examiner is instead applying an improper "obvious to try" rationale in combining the compounds of '648 with SERMs. However, the motivation to utilize the claimed compounds in combination with one or more SERM for contraception is only provided by the Applicants' disclosure.

⁶ *In re Deuel*, 51 F. 3d at 1558-59; 34 USPQ2d at 1215.

⁷ Page 5, paragraph 6, of the Office Action dated October 12, 2006

While one of the skill in the art would recognize that the compounds of '648 and SERMs are *individually* useful for contraception, nothing in the art suggests that a combination of the compounds of '648 and one or more SERM would have any cooperative effect at all. Nor would their combination be logical simply because each agent individually is recognized for contraception.


There are many examples of pharmaceutical agents useful for the treatment of the same disorder, which cannot be combined. Some examples, include coumadin and heparin, which are used as blood thinners, but cannot be combined; and the Tequin® and Erythromycin™ antibiotics, which are used for the treatment of infection, but cannot be combined. It is not predictable based on what is known in the art that the combination of the compounds of '648 and SERMs would have such a synergistic effect. Specifically, one of skill in the art would not have known *a priori* whether a combination therapy utilizing the compounds of '648 and SERMs would produce a better or worse result, or would simply nullify the activity of each agent.

Therefore, no combination of '648 with '562 suggests the present invention. Reconsideration of this rejection is requested.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application, or credit any overpayment in any fees to our Deposit Account No. 08-3040.

Respectfully submitted,

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